

R E M A R K S

Careful review and examination of the subject application are noted and appreciated.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

The rejection of claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54 and 59 under 35 U.S.C. §103(a) as being unpatentable over DeMarzo (U.S. Pat. No. 4,953,552) in view of Beckers (U.S. Pat. No. 5,019,974) is respectfully traversed and should be withdrawn.

The rejection of claims 4-7, 12-15, 22-25, 30, 31, 37, 38, 45-48, and 55-58 under 35 U.S.C. §103(a) as being unpatentable over DeMarzo in view of Beckers (U.S. Pat. No. 5,019,974) and further in view of Reference U is respectfully traversed and should be withdrawn.

DeMarzo concerns a blood glucose monitoring system (Title of DeMarzo). Beckers concerns a diabetes management system and apparatus (Title of Beckers).

In contrast, claim 1 of the present invention provides a blood glucose monitoring system, comprising a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of said blood glucose level, a portable microprocessor-based device that is separate from the blood glucose monitor and includes 1) a video

display for displaying information, the video display configured to display graphic and multi-line alphanumeric information, 2) a plurality of switches operable for interactively controlling the portable microprocessor-based device and for manipulating the information displayed on the video display, and 3) a circuit coupled to the plurality of switches for generating video signals in response to the operation of the switches. Claims 17, 28 and 40 include similar limitations. The combination of DeMarzo and Beckers does not teach or suggest a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of said blood glucose level and a portable microprocessor-based device that is separate from the blood glucose monitor, as presently claimed. As such, the presently claimed invention is fully patentable over the cited reference and the rejections should be withdrawn.

Specifically, both the device of Demarzo and the device of Beckers are stand alone blood glucose measuring devices. At best, the two devices would be viewed by those skilled in the field of the present invention as equivalent devices that could be exchanged for one another. In particular, the device of DeMarzo uses a disposable adhesive patch having a needle type glucose sensor and a second electrode (Abstract of DeMarzo) that produces electrical impulses that are measured by a microprocessor having leads for connection to the electrodes on the patch. The

microprocessor of DeMarzo includes ammeter circuitry for receiving and measuring the electrical impulses from the sensor, and is programmed for calculating an average current value over a specified time period and for displaying that value upon an LCD readout (Column 2, lines 5-28 of DeMarzo). Since the electrodes of DeMarzo produce an analog signal (i.e., current associated with an electrical impulse for which ammeter circuitry is required for receiving and measuring), the electrodes of DeMarzo do not appear to be a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of said blood glucose level, as presently claimed. In fact, not until the microprocessor of DeMarzo receives and measures the analog electrical impulses from the sensor, calculates the average current value over the specified time period, and displays that value upon the LCD readout, does it appear that one could say digitally encoded blood glucose level signals representative of a blood glucose level are produced. Thus, the device of DeMarzo can not be said to teach both a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of said blood glucose level AND a portable microprocessor-based device that is separate from the blood glucose monitor, as presently claimed.

Similar to DeMarzo, the device of Beckers can not be said to teach both a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of said blood glucose level AND a portable microprocessor-based device that is separate from the blood glucose monitor, as presently claimed. In the device of Beckers, the blood glucose test strip reader 60 of Beckers is integrated with the recorder of Beckers (device in FIG. 1 of Beckers). In particular, FIG. 1 of Beckers shows the element 60 as part of the recorder.

Furthermore, neither the device of DeMarzo, nor the device of Beckers has a video display configured to display graphic and multi-line alphanumeric information. FIG. 1 of DeMarzo shows a wristwatch like display that has numbers indicating the level of glucose in the blood and an indicator whether the level is increasing, decreasing, or steady (see column 2, lines 63-65, and column 5, lines 42-53 of DeMarzo). At best, one of ordinary skill in the art would recognize the display of DeMarzo as being a single line seven-segment numeric display. Beckers shows a display that appears to be capable of presenting only fixed symbols and a few numerals. Neither DeMarzo nor Beckers teaches or suggests a programmable microprocessor-based portable unit that is separate from the blood glucose monitor and includes 1) a video display for displaying information, the video display configured to display

graphic and multi-line alphanumeric information, 2) a plurality of switches operable for interactively controlling the programmable microprocessor-based portable unit and for manipulating the information displayed on the video display, and 3) a circuit coupled to the plurality of switches for generating video signals in response to the operation of the switches, as presently claimed. Therefore, the combination of DeMarzo and Beckers does not teach or suggest all the elements of the presently claimed invention as required by MPEP §2143 to meet the Office's burden of factually establishing a conclusion of obviousness. As such, the presently claimed invention is fully patentable over the cited reference and the rejections should be withdrawn.

Furthermore, the Office Action fails to provide a reasonable explanation why the recorder of Beckers must be modified with the current receiving and measuring capability of the monitor of DeMarzo, or the monitor of DeMarzo must be modified with the test strip reading capability of Beckers. The motivation for modifying Beckers provided by the Office ("[to yield] predictable results because the level of ordinary skill in the art demonstrated by the references applied shows the ability to incorporate such data processing features into similar systems") does not appear to necessitate that the monitor in FIG. 1 of DeMarzo and the device in FIG. 1 of Beckers be combined. No explanation is offered for why the monitor in FIG. 1 of DeMarzo or the device in FIG. 1 of Beckers

does not already provide a system for patients with diabetes to track the changes made in health due to changing age or daily routine without any modification. The mere fact that a reference can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination (MPEP §2143.01(III)). Here, the Office appears to be using material that is only taught by the Applicant, against its teacher, which is not proper.

Furthermore, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified or render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification (MPEP §2143.01(V) and(VI)). Separating the recorder and test strip reader portions of the device of Beckers would prevent the automatic operation and storing of blood glucose measurements. Thus, separating the recorder and test strip reader portions of the device of Beckers would appear to make the prior art invention unsatisfactory for the intended purpose or change the principle of operation. Similarly, separating the microprocessor of DeMarzo from the electrode patch would make the monitor of DeMarzo non-functional. Therefore, there does not appear to be a suggestion or motivation for making a modification to either the monitor of DeMarzo or the device of Beckers.

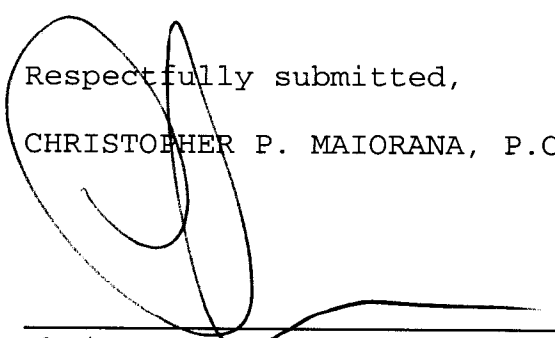
Claims 2-16, 18-27, 29-39 and 41-60 depend, directly or indirectly, from either claim 1, claim 17, claim 28 or claim 40 which are believed to be allowable. As such, the presently claimed invention is fully patentable over the cited references and the rejection should be withdrawn.

Accordingly, the present application is in condition for allowance. Early and favorable action by the Examiner is respectfully solicited.

The Examiner is respectfully invited to call the Applicant's representative at 586-498-0670 should it be deemed beneficial to further advance prosecution of the application.

If any additional fees are due, please charge Deposit Account No. 50-0541.

Respectfully submitted,
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Dated: February 1, 2010

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Docket No.: 04-0410 / 7553.000097